Johnson & Johnson
PHARMACEUTICAL RESEARCH
& DEVELOPMENT, L.L.C.

Food and Drug Administration
Division of Dockets Management
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket Number
2006N-0525

Federal Register Volume 72,
No.3, January 5, 2007 Notice

Dear Sir (or Madam):

Reference is made to the Federal Register Volume 72, No.3, January 5, 2007 Notice, "Supplements and Other Changes to an Approved Application", whereby the FDA is considering possible revisions to 21CFR 314.70. It is our understanding that FDA would like to redefine the post-approval reporting categories with the goal of reducing the reporting burden for certain changes and creating a new reporting category for manufacturing changes that does not require notification. We welcome these changes, as they truly will benefit both the Agency and Industry.

We would like to provide you some comments on a recent post-approval reporting category requested by the FDA, *'CMC Special Reports'* as per 21 CFR 314.81(b)(3)(ii). Within the past six months, the FDA downgraded several of our submissions (i.e., CBE-30s providing an additional analytical laboratory for excipient testing) to *'CMC Special Reports'*. Some details of this new reporting category follow:

a. According to FDA acknowledgment receipts, we were to submit these changes as *'CMC Special Reports'*, as per 21 CFR 314.81(b)(3)(ii), upon implementation of this change. We were then to reference each original CBE-30 and the corresponding *'CMC Special Report'* in the next Annual Report. Thus this type of change resulted in a **3-step process** (CBE-30, *CMC Special Report*, AR listing).

b. At this time use of the *special report* provision (as per 21 CFR 314.81(b)(3)(ii)) requires a **written** request from FDA and thus until the regulation is changed, a direct submission of *CMC* Special *Reports* is not an option.

The request for these additional process steps for this type of change appears to be in direct conflict with the FDA focus on risk-based approaches and reducing the reporting burden. Based on the above we request that the following questions be addressed:

1. If the intent of the S*pecial Report requirement* is to be an additional reporting category, will 21 CFR 314.81(b)(3)(ii) be revised to allow for direct submissions?

2. Is the intent of FDA to update 21 CFR 314.70 with the requirements of the applicability of *CMC Special Reports*?

3. Is the intent of the FDA to create the *CMC Special Report* reporting category, in addition to a new reporting category referenced in the Federal Register Notice Volume 73 No.3 that does not require notification?

Sincerely,

L. Malahias

Lillian Malahias, M.S.
Director
Global Regulatory Affairs, Chem-Pharm